

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

July 16, 2018

Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259)

Dear Administrator Wheeler,

We are writing in regard to the proposed rule for Strengthening Transparency in Regulatory Science (April 30, 2018, 83 Federal Register 18768). The proposed rule stipulates that the U.S. Environmental Protection Agency (EPA) will ensure that the data and models underlying the pivotal science that informs significant regulatory actions are made publicly available, in a format that allows for outside analysis and validation. While that provision is generally consistent with advice from the National Academies of Sciences, Engineering, and Medicine, overly stringent requirements for transparency may cause valid evidence to be discarded and thereby pose a threat to the credibility of regulatory science.

The potential impacts of the proposed rule on the quality of regulatory science will depend on many aspects of the rule's implementation that are not described in detail in the Federal Register notice, including the following:

- (1) Criteria and processes to make objective and transparent decisions about which studies will be included in scientific analyses used to inform federal regulations;
- (2) Approaches for evaluating the data and models used to characterize the dose-response relationships underlying federal regulations; and
- (3) Approaches for protecting the confidentiality of certain kinds of data while balancing the need to make data publicly available.

The National Academies were established by the president of the United States and the U.S. Congress as institutions independent of government to provide objective advice to the nation on matters involving science, engineering, and medicine. The National Academies conduct hundreds of activities and dozens of studies each year to provide advice on a wide variety of issues at the request of EPA and many other federal agencies. The committees that conduct the Academies' studies are carefully selected to provide the best available scientific, technical, and policy expertise while avoiding conflicts of interest. Committee members are experts in their fields who volunteer their time to gather information and review the scientific literature as well as to provide their findings and recommendations to address the issue at hand. These reports are independently peer-reviewed and modified, if necessary, before becoming publicly available.

The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data. We have issued a number of reports, summarized below, that describe how EPA could improve transparency by documenting its procedures and methods for collecting, evaluating, and analyzing data, by specifying assumptions, and by characterizing uncertainties. In particular, the National Academies have provided advice on the transparency, selection, and evaluation of studies used in EPA's regulatory policy formulation.

However, we want to emphasize that although these earlier reports can serve as a valuable resource to help inform decisions about some elements of the proposed rule, they were not designed to address the full breadth of the issues raised by the proposed rule. The proposed rule's scope, complexities, and potential serious implications for regulatory science and action clearly warrant additional thorough, independent, objective, and context-specific evaluation and analysis.

Transparency and Study Selection and Evaluation

The National Academies have carried out numerous studies that advise EPA on the scientific bases of regulatory decisions related to human health and the environment. Examples of relevant reports that advise on dose-response analysis and models, as well as how to perform literature-based reviews, include:

- *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals* (NASEM, 2017a),
- *Review of EPA's Integrated Risk Information System (IRIS) Process* (NRC, 2014),
- *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic: Interim Report* (NRC, 2013),
- *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* (NRC, 2011),
- *Finding What Works in Health Care: Standards for Systematic Reviews* (IOM, 2011),
- *Science and Decisions: Advancing Risk Assessment* (NRC, 2009), and
- *Models in Environmental Regulatory Decision Making* (NRC, 2007).

These reports encourage EPA to consider all available science in the rule-making process and provide guidance about how the agency could be more transparent in describing how evidence is gathered and evaluated. Specifically, systematic-review methods should be adopted to ensure objectivity, rigor, and transparency in performing literature-based reviews (IOM, 2011; NRC, 2011, 2014). NASEM, 2017a, includes four case examples of systematic reviews.

Systematic-review methods should include a strategy for identifying and screening relevant studies and evaluating their quality. The strategy and methods are best established before undertaking the review to ensure objectivity in the search, screening of studies, and to make certain that studies are evaluated consistently. The evaluation criteria should be tailored to the type of evidence under consideration (human, animal, or mechanistic data). Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. If the study data are not available, their

absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment.

The Federal Register notice acknowledges that because of confidentiality concerns, exemptions from the proposed rule will be required because of the impracticality of making publicly available all data that underpin pivotal regulatory science. It is critical for EPA to define what “reasonable effort” would be required to make data publicly available before an exemption is granted. Decisions about exemptions should be based on formal agency guidance and not according to criteria established by a single EPA employee.

Dose-Response Data and Models

Several National Academies reports provide expert advice about how to evaluate dose-response relationships, as is mentioned in the proposed rule. For example, NRC, 2009, recommends that EPA unify the approach it takes to conducting dose-response assessments for cancer and non-cancer health effects, so that potential effects are evaluated based on the probability of harm. This approach will facilitate the assessment of risk management decisions. The recommended unified dose-response approach includes use of a spectrum of data from human, animal, mechanistic, and other relevant studies; a probabilistic characterization of health and environmental risks; explicit consideration of human heterogeneity; characterization of the most important uncertainties; evaluation of background exposure and susceptibility; use of probabilistic distributions when possible; and characterization of sensitive populations.

Making Data Publicly Available

The Federal Register notice cites National Academies reports that provide advice on issues related to data collected and acquired for and by federal statistical agencies to produce national statistics for the public good:

- *Innovations in Federal Statistics: Combining Data While Protecting Privacy* (NASEM, 2017b), and
- *Federal Statistics, Multiple Data Sources, and Privacy Protections: Next Steps* (NASEM, 2017c).

The EPA proposed rule references these reports to identify current approaches for protecting confidentiality while providing data for statistical purposes, such as those used by the Federal Statistical Research Data Centers. The reports consider the kinds of data that are typically collected and acquired under pledges of confidentiality for exclusively statistical purposes – pledges that are backed by strong statutory protections, with criminal penalties for violations.

There are several differences in the confidential microdata collected from individuals and businesses by federal statistical agencies through surveys, versus data and results from the kinds of studies that are within the scope of the EPA proposed rule. These differences have important implications about making data publicly accessible. What works well in the federal statistical environment may not translate effectively to EPA, where stakeholders might be strongly motivated to discount study results that run counter to their regulatory preferences.

In addition, EPA's proposed rule ignores the inherent risks involved in data disclosure, the ever-changing risk landscape, and the efforts needed to mitigate those risks – all of which are discussed in the cited National Academies reports. For example, the security of data held by federal agencies is exposed to new and evolving threats. In addition to cybersecurity concerns, computer scientists and cryptographers have demonstrated that statistical analyses of data sets that generate highly precise results – such as geographic specificity or other characteristics that identify respondents – may result in privacy breaches (NASEM, 2017b; NASEM 2017c). This presents a new challenge that federal statistical agencies are just beginning to address.

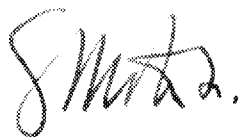
Conclusion

Much more clarity is required on these and many other issues. The potential negative consequences for EPA's ability to take needed regulatory action require more careful examination. We strongly encourage EPA to seek objective, expert guidance on the complexities of this rule and how it would be implemented. As independent and trusted advisers to the nation, the National Academies would be pleased to assist you in this effort.

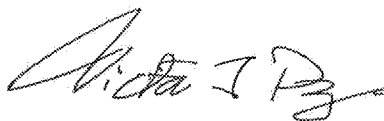
Sincerely,



Marcia McNutt
President, National Academy of Sciences



C. D. Mote, Jr.
President, National Academy of Engineering



Victor J. Dzau
President, National Academy of Medicine